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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,637	04/30/2001	Michael C. Jensen	24751-2502	4845

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/846,637

Applicant(s)

JENSEN, MICHAEL C.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-165 is/are pending in the application.

4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.

- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23-41, 43, 48, 50-54, 63, 73, 74, 81, 82, 85 and 141-143 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-22,42,44-47,49,55-62,65-72,75-80,83,84,86-140 and 144-165.

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DETAILED ACTION

The amendment filed January 2, 2003, amending the specification, and amending claims 11-12, 67-72, 112, 120, 143, 150 and 159, has been entered.

Claims 1-165 are pending.

Election/Restrictions

Applicant's election with traverse of Group III and the altered human IMPDH type II sequence of SEQ ID NO.3 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the examiner has not demonstrated that Groups III-XXVI is independent or distinct. This is not found persuasive because the groups are drawn different enzymes and different conditions. Applicants also argue that the examiner has not demonstrated the linking claims of Groups III-XXVI. This is not found persuasive because the groups are drawn distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected 1-22, 42, 44-47, 49, 55-62, 64-72, 75-80, 83-84, 86-140 and 144-165, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Specification

The sequences in Figure 1 should be identified by SEQ ID numbers and must comply with the Sequence Rules, see 37 CFR 1.821-1.825.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-41, 43, 48, 50-54, 63, 73-74, 81-82, 85 and 141-143 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 23-41, 43, 48, 50-54, 63, 73-74, 81-82, 85 and 141-143, it is unclear what the second cell is comprised of.

Claims 23-41, 43, 48, 50-54, 63, 73-74, 81-82, 85 and 141-143 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: what is comprised in the "conditions that inhibit" the enzyme.

Claims 23-41, 43, 48, 50-54, 63, 73-74, 81-82, 85 and 141-143 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the inhibitors are contacted with the enzyme and how the compositions of claims 41 are exposed to the cells.

In claims 73-74 and 142-143, the exact location of the specific amino acid can be confusing. This rejection can be overcome by amending the claims as "amino acid position 190", for example.

In claims 74 and 143, it is unclear if the claim comprises of three clauses or two. The claim can be interpreted as the nucleic acid comprising (a) or (b) or (c) and a nucleic acid comprising (a) OR (b or c). In the latter interpretation, it is unclear where the nucleotides TCGAGG is located. For rejections of these claims, the former interpretation is used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-40, 43, 48, 50-54, 63, 73-74, 81-82, 85 and 141-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farazi et al. in view of Stratagene Catalog.

Farazi et al. (form PTO-892) teach mutants of human IMPDH type II (abstract and page 961). Farazi et al. teach that inhibitors of IMPDH have antiproliferative activity (page 961). Farazi et al. teach that MPA, MPA derivatives and mycophenolate mofetil are specific inhibitors of IMPDH (page 961). Farazi et al. teach that mutant IMPDH

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confers resistance to and is very useful in anti-infective chemotherapy by designing species-selective IMPDH inhibitors and anti-infective chemotherapy (page 961).

Krystek et al. teach that IMPDH is important for diseases involving proliferation of B and T lymphocytes or viral diseases (Column 1, [0006]). Krystek et al. also teach that tiazofurin, ribavirin and mizoribine are inhibitors of IMPDH. Krystek et al. teach wildtype human IMPDH type II that contains an alanine at position 190 and a Glycine at position 191 and a nucleic acid molecule encoding said enzyme that comprises of the limitations

of claims 73 and 142.

In the state of the art, there are many methods thought which one can ascertain the result of a mutagenized enzyme. One way is to perform cell proliferation assays since inhibitors of IMPDH have antiproliferative activity where resistance against the inhibitors of IMPDH corresponds to an increase in the proliferation of the cells containing the mutant IMPDH.

The difference between the instant invention and the reference of Farazi et al. is that the reference of Farazi et al. does not teach cell proliferation assays.

Stratagene is one of many companies that teach how to perform cell proliferation assays (from PTO-892). Cell proliferation assays are well known in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the mutant of Farazi et al. or to make similar mutant using the wildtype IMPDH taught by Krystek et al. and screen whether the mutants have resistance against inhibitors of IMPDH by performing cell proliferation assays, comparing cells containing the mutant enzymes and cell containing wildtype

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IMPDH. The motivation of performing the cell proliferation assay is to determine if the mutant IMPDH are resistant to IMPDH inhibitors since inhibition of IMPDH results in anti-proliferative activity. Also, IMPDH that are resistant to its inhibitors can be useful in anti-infective chemotherapy by designing species-selective IMPDH inhibitors. One of ordinary skill in the art would have had a reasonable expectation of success since Farazi et al. teach mutant IMPDH that is resistant against its inhibitors and cell proliferation assays are performed routinely in the art.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

February 20, 2003



PONNATHAPU ACHUTAMURTHY
SUPERVISOR
703-308-3804